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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,506	08/19/2003	Jean-Paul Rene Marie Andre Bosmans	JAB-1281-DIV1	5454
27777	7590	01/27/2005	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			CHANG, CELIA C	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,506	BOSMANS ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 27 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of group I in the reply filed on Oct. 27, 2004 is acknowledged. The traversal is on the ground that all the claims have been examined in the parent application. The restriction is therefore withdrawn and all the claims are rejoined.

Claims 1-12 are examined.

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 3-8, 10-12 are rejected under 35 U.S.C. 101 because identical claims have been issued as claims 1-6, 8-10 of US 6,635,643.

3. Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 8-10 of U.S. Patent No. 6,635,643. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are broadened to include the position isomers i.e. 3-OR4. The instant claims therefore included both 3-OR4 and 4-OR4 of the issued claims, thus, fully embraced the issued claims, i.e. issued subgenus fully claimed in the genus of the instant claims.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Daele et al. US 5,374,637 in view of CA 129 (ES patent date 1997), CA 123, supplemented with CA 131 (showing 5HT4 is for colon activity) .

Determination of the scope and content of the prior art (MPEP §2141.01)

Van Daele et al. '637 disclosed analogous compounds having 5HT activity on gastrointestinal track (see whole article especially examples of table 2).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between Van Daele et al. '637 and the instant claims is that the instant claims have the compound with a methylene moiety inserted between the amido linker and the 4-piperidinyl ring. CA 129, CA 123, as supplemented with CA 131 are analogous art since they all disclosed similar compounds for 5HT gastrointestinal activity. CA 129, CA 123 each exemplified compounds with or without the methylene insertion together with variations of R1-R2 ring size, of the OR4 being at 3- or 4- positions.

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art would be aware of all the pertinent art in the field. The above references places the basic compound structure with the modification of one methylene insertion or variation of OR4 at different position, in the possession of artisan in the field. The modification of one proven compound with merits of analogous compound for the same utility is considered prima facie obvious. Especially, the modification are well recognized in the art to be obvious variation for pharmaceutical compounds. In re Ruddy 121 USPQ 427 (methylene insertion obvious, In re Mehta 146 USPQ 284, position isomerism is a fact of close structure).

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over King et al. US 6,172,379 in view of CA 129, CA 123, CA 131 (see explanation supra) further in view of Van Daele et al. US 5,374,637 vs Van Daele et al. US 5,948,794

Determination of the scope and content of the prior art (MPEP §2141.01)

King et al. '379 disclosed structurally analogous compounds for 5HT gastrointestinal activity (see col. 14-16, claims 1-11).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between king et al. '379 and the instant claims is that the piperidinyl ring of the instant claims is OR4 substituted while the king '379 has an unsubstituted piperidinyl ring. Per ponderous of references recited in CA 129, CA 123, CA 131 and Van Daele et al. US 5,374,637 vs Van Daele et al. US 5,948,794 showed that the substitution on the piperidinyl ring with or without OR4 is an optional choice for such compounds and the substitution can be at 3- or 4-position of the piperidinyl ring (CA 123 vs CA 129).

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art is deemed to be aware of all the pertinent art in the field. The above references placed the optional choice of 3- or 4-position OR4 substitution in the possession of artisan in the field. The per ponderous of such variation of the art in similar compounds would motivate one skilled in the art to employ such modification since it is well recognized in the art that such modification will render the modified compounds having similar activity for gastrointestinal utility.

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6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See US 6,172,062 which disclosed structurally close compounds without the OR4 substitution together with more limited sulfonyl linked substituents for "L".

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Jan. 24, 2005


Celia Chang
Primary Examiner
Art Unit 1625